OCT - 4 2001

510(K) Summary

Disc-O-Tech Medical Technologies, Ltd.
Fixion Interlocking Proximal Femoral Intramedullary Nailing System

Company Name

Disc-O-Tech Medical Technologies, Ltd.
3 Hasadnaot St., Herzelia, 46728, Israel

Submitter's Name and Contact Person

Elad Magal
Disc-O-Tech Medical Technologies, Ltd.
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Date Prepared

August 2001

Trade/Proprietary Name

Fixion™ Interlocking Proximal Femoral Intramedullary Nailing System (Fixion PF)

Classification Name

Intramedullary Fixation Rod
21 CFR § 888.3020
Class II

Predicate Devices

1. Fixion Interlocking PF Intramedullary Nailing System (K010988) by Disc-O-Tech
2. Fixion Intramedullary Nailing System (K990717, K003212, K003215, K010901) by Disc-O-Tech
3. Fixion Interlocking Intramedullary Nailing System (K002783) by Disc-O-Tech.
4. Proximal Femoral Nail (K970097) by Synthes.

Performance Standards

The following standards were used:

1. The Fixion PF Nail is manufactured from 316L Stainless Steel, which meets the requirements of ASTM F138 - Standard Specification for Stainless steel Bar and Wire for Surgical Implants.
2. The Fixion PF Nailing System accessories incorporate surgical grade stainless steel and silicone.
3. The Fixion PF Nail is designed to meet the requirements of ASTM F565 – Standard practice for Care and Handling of Orthopedic Implants and Instruments.
4. The 4 point bending mechanical testing was performed according to ASTM

F1264-99 - Standard for Mechanical Performance Considerations for Intramedullary Fixation Devices.

5. The Hip Peg testing was performed according to ASTM F384-99 – Standard Specification for Metallic Angled Orthopedic Fracture Fixation Devices.

Intended Use

The *Fixion Interlocking Proximal Femoral Nailing System* ("Fixion PF") is intended for use in fixation of fractures in the femur. The Fixion PF is indicated for use in fractures in the femur shaft, proximal femoral fractures, and combinations of these fractures. Proximal femoral fractures include stable and unstable pertrochanteric, intertrochanteric and subtrochanteric (with and without break-off of the minor trochanter), high subtrochanteric fractures and combinations of these fractures. The long Fixion PF may also be used in mid shaft fractures, 5cm below the surgical neck to 5cm proximal to the distal end of the medullar canal.

The Fixion PF is also indicated for use in osteotomy, nonunions and malunions, bone reconstruction following tumor resection, grafting and pathological fractures, revision procedures.

System Description

The Fixion Intramedullary Proximal Femoral Nailing System consist of the following main components:

1. The **Nail Implant** is an expandable non-slotted stainless steel cylindrical tube, with a cap protected, female threaded proximal end with holes for Femoral Neck Peg (Hip Peg) and Hip Pin. Other implantable components provided are the Femoral Neck Peg (Hip Peg) and the Hip Pin.
2. The **Instrument Set** consists of a few accessories used during insertion and removal (if required) of the implant.
3. The **Inflation Device (Pump)** is a single-use manual plastic pump that is filled with sterile inflation liquid and used to expand the Nail implant and Femoral Neck (Hip) Peg

Once the Nail and the Femoral Neck Peg are positioned within the medullary canal and femur neck respectively, rotation of the pump handle allows for peg and nail diameter increase to their intended diameter under x-ray and controlled pressure. The Hip Pin may be inserted as well.

Substantial Equivalence

The Fixion PF Nail is substantially equivalent to the Fixion PF Nail currently cleared for marketing under 510(k) K010988.

The modified Fixion PF Nail has the following similarities to that which previously received 510(k) concurrence:

- Has the same intended use
- Basically has the same operating principles
- Basically incorporates the same design

- Incorporates the same materials and processes
- Is sterilized and packed, basically, in the same manner.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 4 2001

Mr. Elad Magal
General Manager
Disc-O-Tech Medical Technologies, Ltd.
3 Hasadnaot Street
Herzelia, 46728
Israel

Re: K012967
Trade/Device Name: Fixion™ Interlocking Proximal Femoral Intramedullary Nailing System
Regulation Number: 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: August 30, 2001
Received: September 4, 2001

Dear Mr. Magal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K012967

Device Name: Fixion™ Interlocking Proximal Femoral Intramedullary Nailing System

Indication for Use:
The *Fixion Interlocking Proximal Femoral Nailing System* ("Fixion PF") is intended for use in fixation of fractures in the femur. The Fixion PF is indicated for use in fractures in the femur shaft, proximal femoral fractures, and combinations of these fractures. Proximal femoral fractures include stable and unstable pertrochanteric, intertrochanteric and subtrochanteric (with and without break-off of the minor trochanter), high subtrochanteric fractures and combinations of these fractures. The long Fixion PF may also be used in mid shaft fractures, 5cm below the surgical neck to 5cm proximal to the distal end of the medullar canal.

The Fixion PF is also indicated for use in osteotomy, nonunions and malunions, bone reconstruction following tumor resection, grafting and pathological fractures, revision procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over the Counter Use _____
(per 21 CFR 801.109)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

--CONFIDENTIAL-

510(k) Number K012967